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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,709

10/17/2003

Robert H. Harris

13095A

2201

7590

05/15/2006

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,709

Applicant(s)

HARRIS, ROBERT H.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,25-34,56,63-67 and 73-103 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 20, 21, 25-34, 56, 63-67, 73-103 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 3/3/06, claims 25-28, 63, 86, 88, 89, 102 have been amended. Claims 20, 21, 25-34, 56, 63-67, 73-103 remain pending.

Applicants' arguments filed 7/18/05 have been considered and found persuasive in part. The previously imposed rejection of claims 25-28, 63, 74, 88, 89, 102 under 35 U.S.C. §112 second paragraph is withdrawn.



35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 20, 21, 25-34, 56, 63-67, 73-103 are rejected under 35 USC §101 because the claimed invention is not supported by a well established utility.

As indicated previously, the claims are drawn to a method for "prophylaxis" of migraine headaches. This term implies that headaches can be prevented. The term implies a 100% success rate. Suppose that, for example, one of the claimed compounds were administered to each of 1000 persons who had, in the past, shown a pronounced propensity for migraine headaches. If as a result of the administration, 999 of the patients never again developed a headache of any kind, and such a result would be wildly successful by any standard. But such a result would actually

provide evidence that prevention had not been achieved. Applicants' data falls far short of the "bar" that would have to be overcome in demonstrating prevention or prophylaxis. Consider the following:

- Goldstein D. J. (*Cephalalgia : an International Journal of Headache* 17 (7) 785-90, 1997) discloses (last paragraph of the last page of the article) that "existing ...migraine therapies are not effective in treating every migraine for any specific individual, and are differentially effective..."
- Brandes Jan L (*Headache* 44 (6) 581-6, 2004) discloses (page 585, col 2) that an earlier study had found montelukast to be therapeutically effective in treating migraines. Brandes also conducted a study in which many of those receiving the compound reported efficacy in the treatment of their headaches. Yet the study also found that montelukast was clearly not effective in preventing headaches.

These references support the proposition that if one begins with the premise that a given compound is effective to "treat" migraine headaches, it does not follow therefrom that the compound will prevent headaches. The examiner has thus met his burden in raising doubt about the veracity of applicants' proposition.

In response to the foregoing, applicants have argued that other examiners have abstained from rejecting claims which recite the term "prophylaxis", and that because some examiners have abstained from such a rejection, it follows that all other examiners who have imposed this rejection (or are presently imposing this rejection) are "wrong". First, it is not true that the actions taking by one examiner in a given application impose upon all subsequent examiners the obligation

to abstain from imposing a rejection in a similar situation. But even if there were some sort of court opinion or statute that held this to be true, the fact is that there exist (and have existed) many other examiners who have imposed such a rejection in other applications; one cannot determine from reading a patent which rejections were imposed. Thus, according to applicants own reasoning, those who abstained from imposing such rejections were “wrong”. Applicants have also argued in effect that the USPTO is a monolithic entity, and that if one examiner abstains from imposing a rejection in a given situation, that decision by that one examiner represents the views of all examiners. However, it is no more true that any one examiner represents the views of the USPTO than it is that any one justice represents the views of the U.S. Supreme Court.

Applicants have also attempted a semantic analysis with regard to the term at issue (“prophylaxis”). Applicants have pointed to a passage in Silberstein (*American Academy of Neurology*, 2000) which states that one of the “goals” of migraine preventative therapy is to reduce attack frequency. Actually, the examiner does not dispute this particular statement, phrased as it is. However, there are two issues. First, if a person states that his “goal” is to achieve “X”, that is quite different from stating that he absolutely and definitely will achieve “X”. Many people, for example, have the goal of retiring by age 55, or have the goal of financial independence. Having a goal and realizing it are two very different things. The claims at issue are not about goals, they are about assertions as to what can be

achieved. There is a second issue, which is that a given term can have more than one meaning, or more than one shade of meaning. Perhaps it is true that one of the meanings of the term “prophylaxis” is to reduce the incidence of a given disease. But that does not mean that the term does not encompass another meaning. The Webster’s dictionary lists the following as one of the meanings of the term “prophylactic”: *guarding from or preventing disease*. Does that mean that all other definitions are necessarily excluded? Of course not. But the issue here is what the term encompasses. If applicants had wanted to distinguish a method of reducing the frequency of migraine headaches from a method of preventing them, applicants had this option at the time the application was filed. Applicants have declined this option. Accordingly, it now becomes a subject of debate as to what the term encompasses. The examiner maintains that the term at issue encompasses an assertion of prevention, even if it is true that that the term at issue may also encompass an assertion of reducing the incidence of headaches.

Applicants have also attempted to dismiss the teachings of Goldstein D. J. (*Cephalalgia : an International Journal of Headache* 17 (7) 785-90, 1997) and of Brandes Jan (*Headache* 44 (6) 581-6, 2004). As indicated previously, Goldstein states that “existing ...migraine therapies are not effective in treating every migraine for any specific individual, and are differentially effective...” Applicants have argued essentially that the fact that treatment of migraines often fails does not in any way undermine the assertion that migraines can be prevented. The

examiner would disagree. As it happens, treatment of a disease, however difficult, is more easily achieved than prevention. If one cannot succeed in treating a disease, then there is little hope for prevention. Applicants have also argued that the compounds disclosed in Goldstein are not the same as those to which the claims are directed. Applicants have also attempted to dismiss the teachings of Brandes on this basis. However, according to applicants line of reasoning, all of the articles and patents to which applicants have referred are also irrelevant, since they disclose compounds which are different from those claimed.

Thus, (a) the definition of prophylaxis to which applicants have pointed discusses the word at issue in terms of "goals" or "ideals", as opposed to what applies in the case of the instant claims, which make blanket assertions as to what can be achieved; (b) applicants have presented no evidence which would support the notion that the term at issue excludes the dictionary definition, which makes reference to "prevention", and (c) the articles to which applicants have referred disclose compounds which are different from those claimed; by applicants own reasoning these articles should be dismissed as irrelevant.

Claims 20, 21, 25-34, 56, 63-67, 73-103 are also rejected under 35 USC §112 first paragraph. Specifically, since the claimed invention is not supported by a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER